October 8, 2021

Kerberos Proximal Solutions, Inc.
Tom Mason
Vice President, RA & Qa
10600 North Tantau Ave.
Cupertino, California 95014

Re: K050130
Trade/Device Name: Kerberos Proximal Solutions Rispiration System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Tom Mason:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 13, 2005. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.10.08 10:31:34 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2005

Kerberos Proximal Solutions
C/O Mr. Tom Mason
Vice President, Regulatory Affairs and Quality Assurance
10600 N. Tantau Avenue
Cupertino, CA 95014

Re: K050130
Trade/Device Name: Kerberos Proximal Solutions Rinspiration System
Regulation Number: 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: II
Product Code: DXE
Dated: April 8, 2005
Received: April 11, 2005

Dear Mr. Mason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The Kerberos Proximal Solutions Rinspiration System may result in secondary removal of thrombus while using the Rinspiration System in a manner consistent with the indications and instructions for use presented in the product labeling; however, please note the following: The safety and effectiveness of the Kerberos Proximal Solutions Rinspiration System has NOT been established for the exclusive or sole use of thrombectomy or embolic protection. Complications

from the use of this device in this manner could lead to death, permanent impairment, and/or the need for emergency medical intervention.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4

# Indications for Use

510(k) Number (if known): K050130

Device Name: Kerberos Proximal Solutions Rinspiration System

Indications for Use:

The Kerberos Proximal Solutions Rinspiration System is intended to infuse physician specified fluid and remove/aspirate fluid, fresh, soft emboli and thrombi from the coronary and peripheral vasculature.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5/12/05

K050130



## SECTION 8

### 510(k) Summary of Safety and Effectiveness

This 510(k) summary for the KPS Rinspiration System is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**Applicant Information**

MAY 13 2005

Kerberos Proximal Solutions, Inc.
10600 North Tantau Avenue
Cupertino, CA 95014

Contact Person: Tom Mason
Phone Number: (408) 253-3319
FAX Number: (408) 253-6118

**Device Information**

Classification: Class II
Trade Name: KPS Rinspiration™ System
Generic/Common Name: Embolectomy Catheter (21 CFR 870.5150)

**Predicate Devices**

The subject device is substantially equivalent in intended use and/or method of operation to the following cleared devices.

(1) Kerberos Proximal Solutions Rinspiration System (Coronary/Peripheral) K041123
(2) Medtronic Export Catheter K040869
(3) Vascular Solutions, Inc., PRONTO Extraction Catheter K032763
(4) Kerberos Proximal Solutions Rinspiration System (Peripheral) K041291

**Intended Use**

The Kerberos Proximal Solutions Rinspiration System is intended to infuse physician specified fluid and remove/aspirate fluid, fresh, soft emboli and thrombi from the coronary and peripheral vasculature.

**Device Description**

The system consists of a Rinspiration™ Catheter, and a Rinspirator™ with accessories. The Rinspiration Catheter is a multi-lumen, rail configuration catheter that has perforations located near the distal end of the catheter to dispense an infusible fluid. The Rinspiration Catheter will be placed in the vasculature of a patient over a guide wire. The Rinspiration Catheter is offered with a standard tip and a short tip. The catheter includes a radiopaque marker band at the distal tip and two radiopaque marker bands designating the infusion portion of the catheter. The catheter has a hub on the proximal end that allows access to the infusion and aspiration lumens. The Rinspirator and accessories is a sterile, single-use mechanical device. This hand activated device allows for simultaneous infusion and aspiration of fluids at the treatment site. The device activates two syringes, one for infusion and one for aspiration. This simultaneous infusion and aspiration action is known as "Rinspiration."

**Substantial Equivalence**
The KPS Rinspiration System is substantially equivalent to the predicate devices with regard to intended use, function, materials, and sterilization method.

All necessary testing was performed on the KPS Rinspiration System to ensure the product is substantially equivalent to the predicate devices and to ensure that the KPS Rinspiration System does not have any differences that have a significant effect on safety or effectiveness.

**Functional Test Results**
Functional testing was conducted on the KPS Rinspiration System to ensure that the product will function according to its Instructions for Use. This functional testing was performed per KPS protocol and referenced International Standard *ISO 10555, Sterile, Single Use Intravascular Catheters - Part 1.* All testing conducted confirmed the acceptability of the KPS Rinspiration System to perform as intended.

**Biocompatibility and Sterility**
Biocompatibility testing was conducted on the KPS Rinspiration System materials to ensure acceptability when used as directed. The KPS Rinspiration System materials passed the necessary biocompatibility tests, complying with *ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing requirements.*

Sterilization Validation was conducted according to ISO 11135, *Industrial Ethylene Oxide Sterilization, Validation and Routine Control*, on the KPS Rinspiration System to assure a sterility assurance level (SAL) of $10^{-6}$.

**Summary**
Based on the intended use, product performance and biocompatibility information provided in this notification, the subject device is safe and effective when used in accordance with its Instructions for Use and has been shown to be substantially equivalent to currently marketed predicate devices.